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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,183	09/29/2003	William T. Donofrio	END 5031	1957

27777 7590 10/20/2005  
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EXAMINER

ROY, ANURADHA

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/674,183

**Applicant(s)**

DONOFRIO ET AL.

**Examiner**

Anuradha Roy

**Art Unit**

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/17/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6 - 8, 11, & 19 is/are rejected.
- 7) ☒ Claim(s) 3, 5, 9, 10, 12-18, & 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/12/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 2, 6 & 7 rejected under 35 U.S.C. 102(b) as being anticipated by Hickie (US Patent No. 6,745,764).

Regarding claim 1, Hickie discloses a conscious sedation system comprising: a) a controller (14) which generates a request for a predetermined response from a patient and which analyses at least a response made by the patient to the request to determine a level of sedation of the patient; and b) a response testing apparatus (256, 264, & 266) including: (1) a request assembly (256 & 264) which audibly communicates to the patient the request generated by the controller and which includes a non-ear-canal-contacting speaker (450,452, & Figures 15&16); and (2) a response assembly (256 & 254) which senses the response and which communicates the response to the controller.

In regard to claims 2 & 7, Hickie discloses a conscious sedation system wherein the speaker, when disposed on the patient proximate a bone of the patient, audibly communicates the request to the patient at least in part by bone conduction of audible sound (452). The examiner is contending that that the three ear bones (malleus, incus, and stapes) perform the bone conduction of the audible sound.

Regarding claim 6, Hickie discloses a request assembly (256 & 264) for a response testing apparatus for a conscious sedation system, wherein the conscious

sedation system includes a controller (14) which generates a request for a predetermined response from a patient, and wherein the request assembly comprises a non-ear-canal-contacting speaker (450,452, & Figures 15&16) which audibly communicates to the patient the request generated by the controller.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4, 8, 11, & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickie in view of Foremann et al (US Publication No. 2002/0150819).

Hickie discloses a conscious sedation system comprising: a) a controller (14); and b) a response testing apparatus (256, 264, & 266) including: (1) a request assembly (256 & 264) which audibly communicates to the patient the request generated by the controller and which includes a non-ear-canal-contacting speaker (450,452, & Figures 15&16); and (2) a response assembly (256 & 254). However Hickie does not disclose the use of a skull cap in the request assembly. Foremann et al., however, discloses a skull cap. Foremann et al. discloses a request assembly wherein the request assembly includes a skull cap (headband in Figure 1) worn on the head of the patient, wherein the speaker (12 or 13) is attached to the outside of the skull cap, and wherein the inside of the skull cap covers an ear of the patient, and the speaker is substantially aligned with the ear canal of the patient. Additionally, Foremann et al. discloses a request assembly which includes a skull cap (headband in Figure 1), wherein the speaker (12 or 13) is

attached to the headband, and wherein, when the headband is worn by the patient. Additionally, the speaker is capable of contacting the side of the head of the patient above the ear by adjusting the level. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the earpiece (Figure 15 &16) in the request assembly disclosed by Hickie to a skull cap to allow for more secure fit for the assembly.

Hickie discloses a request assembly for a response testing apparatus capable of being used for a conscious sedation system, wherein the conscious sedation system includes all of the aforementioned elements. However, Hickie does not disclose a request assembly comprising a sound tube having one end disposable proximate an ear canal or a microphone of an assistive hearing device of the patient and having another end disposable proximate the speaker. However, Foreman et al. discloses a request assembly comprising a sound tube having one end disposed proximate an ear canal (tube leading out of 12) and having another end disposable proximate the speaker (tube leading to 13)

#### **Allowable Subject Matter**

Claims 3, 5, 9, 10, 12, 13, 14, 15, 16, 17, 18, & 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **Conclusion**


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bennett (US Patent No. 5,195,531) and Tsutsumi et al. (US Patent No. 6,315,736) disclose a system in determining a level of consciousness in a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~



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